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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,030	11/25/2003	Marcus Pfister	P03,0472	6512

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EXAMINER	
LUONG, PETER	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,030	PFISTER ET AL.	
	Examiner	Art Unit	
	Peter Luong	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/25/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not disclosed, to one of ordinary skill in the art, how the modeling of the tissue is obtained without undue experimentation. Furthermore, applicant has claimed detecting fluorescence-excited light as a two-dimensional measurement value (claim 9, 2nd paragraph) and emitting a three-dimensional location (claim 9, 3rd paragraph) but has not disclosed how to obtain a three-dimensional location from a two-dimensional measurement value.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 5,999,836) in view of Sholz ("Towards Virtual Electrical Breast Biopsy: Space-Frequency MUSIC for Trans-Admittance Data", IEEE Trans. Med. Imag., Vol. 21, No. 6, pp. 588-595).

5. The device of Nelson et al. inherently discloses the method steps to spatially localize a region in a biological tissue section (abstract and col. 8, ln. 18-20) that, at least during an examination, exhibits a fluorescence property different from the tissue section (the properties are modified by the tissue through which the beam passes, column 18, lines 9-14), due to which, given an exposure with light of a first wavelength (claim 21 step 3), light of another wavelength is emitted (claim 21 step 6), comprising the steps of: applying a sequence of fluorescence-exciting light signals at different locations on the tissue-section (claim 21, step 3), generating the fluorescence-exciting light signals with various modulation frequencies and radiating the light signals into the tissue section (column 15, lines 58-66), measuring fluorescence light arising due to the light signals, at a plurality of measurement locations on a surface of the tissue section, and thereby obtaining response signals (claim 21 step 6), determining frequency-independent signal portions (column 18, lines 9-12) in the response signals and further processing the frequency-independent signal portions (column 18, lines 9-12) into input values for localization (claim 21 step 7), marking the regions with fluorescing markers to generate the various fluorescence properties (column 9, lines 65-67 through column 10, lines 1-4), and radiating the fluorescence- exciting light signals as laser light of suitable wavelength (column 15, lines 58-60). Nelson et al. also discloses a device for spatially localizing a region in a biological tissue section (abstract and col. 8, ln. 18-20) that at least during an examination, exhibits a fluorescence property different from the tissue section (column 18, lines 9-14), said device comprising an arrangement of light sensors 110 distributed on a surface of the tissue section (it would be obvious to one of ordinary

skill in the art to move the sensors such that the sensors would be in contact with the surface of the tissue, column 14, lines 3-5 and figures 1b, 2b, and 2c), a laser diode arrangement 112 that emits fluorescence-exciting light that interacts with a fluorescing marked region in the tissue section (column 9, lines 65-67 through column 10, lines 1-4), causing the marked region to emit fluorescence-exited light that is detected by the light sensors 110 in a two-dimensional measurement value distribution, said light sensors 110 generating response signals corresponding to said two-dimensional measurement value distribution (images are produced by the response signals, column 15, lines 57-63), and a processor (response signals are analyzed by a computer, column 5, lines 62-65) supplied with said response signals, said processor being configured to determine frequency-independent signal portions (column 18, lines 9-12) in the response signals and to further process the frequency-independent signal portions (column 18, lines 9-12) into input values for localization (column 5, lines 62-65), the arrangement of light sensors 110 comprises a first set of light sensors 110 and a second set of light sensors 110 adapted to be respectively disposed on opposite sides of said tissue section (column 14 lines 66-67 through column 15, lines 1-3, and figure 12), comprising an x-ray mammography apparatus having two compression plates 102, and wherein said light sensor arrangement 110 is Integrated into at least one of said compression plates 102 (figure 1b), the arrangement of light sensors 110 comprises a curved mounting 118 for said light sensors (contoured compression plates 118, figure 13a and 13b). Nelson et al. also discloses the arrangement of light sensors 110 comprises a flexible mounting (column 21, lines 58-60 and 65-67, and figure 20).

6. The patent of Nelson et al. does not disclose the method steps of modeling the tissue section and determining a set of guide fields from the model, and transforming the guide fields and comparing the input values processed from the frequency-independent signal portions with the transformed guide fields, and emitting a three dimensional location of the transformed guide fields that best reproduces the frequency-independent signal portions as a three dimensional location of the region to be localized, normalizing said guide fields, transforming the guide fields into orthogonal guide fields, determining the orthogonal guide fields from the guide fields by a singular-value decomposition, and determining optical parameters with reference measurements in non-fluorescence-exciting wavelengths by estimation. Nelson et al. also does not disclose a processor for modeling the tissue section and determining a set of guide fields from the model, transforming the guide fields and comparing the input values processed from the frequency-independent signal portions with the transformed guide fields, and emitting a three dimensional location of the transformed guide fields that best reproduces the frequency-independent signal portions as a three dimensional location of the region to be localized.

7. However, the publication to Scholz teaches the method steps of modeling the tissue section and determining a set of lead fields from the model (abstract), and transforming the lead fields (section B last paragraph), emitting a three dimensional location (abstract, line 4) of the transformed lead fields that best reproduces the frequency-independent signal portions as a three dimensional location (abstract, line 4) of the region to be localized (section C), normalizing said lead fields (section C

paragraph 2), transforming the lead fields into orthogonal lead fields (section C paragraph 2), and determining the orthogonal lead fields from the lead fields by a singular-value decomposition (section B). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the method of tissue localization by electrical immittance measurements taught in the publication to Scholz to the device of Nelson et al. to improve breast cancer diagnosis (Scholz, abstract, lines 1-2). Furthermore, Nelson et al. discloses that electromagnetic properties of various normal and diseased breast tissues exhibit wavelength dependence and examining the effects of tissue on other electromagnetic parameters may aid in distinguishing between various types of tissues (Nelson et al., column 7, lines 21-27), therefore one of ordinary skill in the art would recognize that by comparing the results from the device of Nelson et al. and Scholz, breast cancer localization can be enhanced. The modified device of Nelson et al. in view of Scholz would then render obvious the method steps of comparing the frequency-independent signal portions with the lead fields, emitting a location of the transformed lead fields that best reproduces the frequency-independent signal portions, and determining optical parameters with reference measurements in non-fluorescence-exciting wavelengths.

Response to Arguments

8. Applicant's arguments filed 12/19/2007 have been fully considered but they are not persuasive.

9. Applicant contends that Nelson et al. does not disclose spatially localizing a region in a biological tissue and the 2D image produced by Nelson et al. does not allow

for spatial localization of a lesion. However, the applicant's interpretation of the term "spatially" to mean identification in space, more specifically three-dimensions is incorrect. The Examiner's takes the position on space to mean any of a linear distance (one-dimensional), an area (two-dimensional), and volume (three-dimensional) as evidenced by the definition of "space" by Dictionary.com. Furthermore, applicant's interpretation that Nelson et al. does not allow for spatial localization, i.e. three-dimensional location, is incorrect. The Examiner directs the applicant to the passage of Nelson et al. (col. 8, ln. 18-20) which cites "two dimensional images may be obtained simultaneously, thereby providing a three dimensional image of the object". Therefore, Nelson et al. discloses a system capable of locating lesions in three dimensions. Furthermore, applicant has amended the claims to clarify **"the result of a three-dimensional location of the transformed lead fields** that best reproduces the frequency-dependent signal portions as a three-dimensional location of the region to be localized" (page 11, lines 16-18 of applicant's response). However, the three-dimensional location is of the lead fields as stated in applicant's response and recited in the claims. The Examiner directs the applicant to the passage of Scholz (abstract, line 4) which teaches determining a three-dimensional position from the lead fields as relied upon in the above rejection.

10. Applicant also argues that Nelson et al. does not make any use of fluorescence in generating the image. However, the Examiner takes the position that Nelson et al. does make use of fluorescence in generating the image. The Examiner directs the applicant to the passage of Nelson et al. (col. 9, ln. 65 to col. 10, ln. 4, which was also

previously cited in the previous office action, page 6, lines 9-10) which cites "if the tissue volume of interest contains contrast-enhancing materials or materials which can be **detected through emission fluorescence** or Raman scattering or Doppler effects, then the use of multiple collimated angled beams may improve localization capabilities". Therefore, Nelson et al. discloses its system detects emission fluorescence.

11. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

12. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion to combine the references can be found in both Nelson et al. (column 7, lines 21-27) and Scholz (abstract, lines 1-2), as stated in the previous office action. Nelson et al.

suggests that electromagnetic properties of various normal and diseased breast tissues exhibit wavelength dependence and examining the effects of tissue on other electromagnetic parameters may aid in distinguishing between various types of tissues. Scholz suggests the method taught can improve breast cancer diagnosis. Therefore, one of ordinary skill in the art at the time the invention was made would have recognized that by comparing the results from the devices of Nelson et al. and Scholz, breast cancer localization can be enhanced.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571)270-

1609. The examiner can normally be reached on Monday - Thursday, 9:30 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

/P.L./